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REMARKS

The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Applicants assert that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

Status of Application and Claims

In the October 5, 2006 Response, in response to a restriction requirement, Applicants elected for examination Group I, consisting of claims 1-25, 29, 38, 39 drawn to a method of treating a mammal, canceled claims 26 and 30, and amended claims 27, 28, 31 and 34-37. In response to an election of species requirement, Applicants also elected, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable, the following species:

- the treatment of Diabetes as the specific objective,
- recombinant human Insulin as the specific insulin type, and
- the formulation of recombinant human Insulin, 4-CNAB and pharmaceutically acceptable excipients as the contents of the formulation.

. In the Office Action, the Examiner acknowledged Applicants' election of Group 1 (claims 1-25, 29, 38, and 39, limited to G1) and the elected species. The Examiner indicated that claims 1, 5-25, 27, 28, 31-34, and 36-39 were examined in this Office Action and that claims 2-4, 29 and 35 are withdrawn.

Claim Objections

In the Office Action, the Examiner objected to Claim 21 due to a typographical error. Applicants have amended Claim 21 to recite "said oral administration" instead of "said orasl administration". Accordingly, Applicants request withdrawal of the objection.

The Office Action Summary sheet indicated that claims 23-25 and 32-34 were objected to. Because these claims were not specifically discussed in the Office Action and they were not

rejected, Applicants assume that these claims were objected to as being dependent upon a rejected base claims but would be allowable if rewritten in independent form including all the limitations of the independent base claims and any intervening claims. Applicants thank the examiner for his indication of allowable subject matter.

35 U.S.C. § 103 Rejections

In the Office Action, the Examiner rejected Claims 1, 5-22, 27, 28, 31, and 36-39 under 35 U.S.C. §103 as being obvious:

(a) over U.S. Patent No. 7,137,951 to Pilarski in view of U.S. Patent No. 7,118,762 to Byrd, or U.S. Patent No. 7,115,663 to Moye Sherman, or U.S. Patent No. 7,084,114 to Ekwuribe, or U.S. Patent No. 7,060,675 to Ekwuribe. According to the Examiner, Pilarski discloses administration of insulin at bedtime, but does not specify oral insulin. The Examiner asserts that each of Byrd, Moye-Sherman, Ekwuribe '114 and Ekwuribe '675 disclose oral administrable forms of insulin.

(b) over U.S. Patent No. 7,060,675 to Ekwuribe. According to the Examiner, Ekwuribe discloses orally administrable insulin and that said administration could be at bedtime.

(c) over Miller et al. (Clinical Pharmacology and Therapeutics 53(3), 380-4, 1993) in view of Mesiha et al. (International Journal of Pharmaceutics 249(1-2), 1-5, 2002), Hosny et al. (International Journal of Pharmaceutics 237(1-2), 71-6, 2002), or Clement et al. (Diabetes Technology & Therapeutics 4(4), 459-66, 2002. According to the Examiner, Miller et al. disclose that administering insulin at bedtime could be beneficial but does not disclose oral administration of insulin, and each of Mesiha et al., Hosny et al. and Clement et al. disclose orally administering insulin.

(d) over Yki-Jarvinen et al. (Annals of Internal Medicine 130(5), 389-96, 1999) in view of Mesiha et al., Hosny et al., or Clement et al. According to the Examiner, Yki-Jarvinen et al. disclose that administering insulin at bedtime could be beneficial but does not disclose oral administration of insulin, and each of Mesiha, Hosny and Clement disclose orally administering insulin.

With regard to the priority applications of the present application, the Examiner asserted that "the instantly claimed invention is not described in any of the [priority] provisional applications," because "[t]he provisional applications make reference to "nighttime," but not "bedtime." Applicants dispute the Examiner's characterization of the priority provisional applications and note that it is plainly incorrect, because all three of the priority provisional applications do recite "bedtime" in the claims. Applicants point out that both the specification and claims of each of U.S. Patent Applications 60/438,195, 60/438,451 and 60/478,967 do in fact refer to oral administration of insulin "at bedtime", and the instant application is entitled to claim priority from those provisional applications.

As stated previously, the Examiner did not object to or reject claims 23-25 and 32-34, and Applicants understand that these claims would be allowable if rewritten in independent form including all the limitations of the independent base claims and any intervening claims. Accordingly, Applicants have amended claims 1 and 16 to incorporate the limitations of claims 332 and 23 (which have herein been canceled), respectively, namely that the pharmaceutical formulation being administered at or shortly before bedtime comprises an effective amount of a pharmaceutically acceptable delivery agent comprising 4-CNAB which facilitates absorption of said insulin from the gastrointestinal tract of said mammals. In view of these amendments to claims 1 and 16, Applicants believe that amended claims 1 and 16, as well as their dependent claims 5-22, 24, 27, 28, 33 and 36-39, should be allowed, and Applicants respectfully request that they be passed to allowance.

In addition, Applicants have amended claims 25 and 34, which were indicated as being allowable, by incorporating within them the limitations of base claims 16 and 1, respectively, prior to their amendment herein. Furthermore, Applicants have added new claims 40-49 and new claims 50-67, which depend from new claims 25 and 34, respectively, and which correspond to certain of the existing claims that currently depend from claims 1 and 16. In view of these amendments to claims 25 and 34, Applicants believe that amended claims 25 and 34, as well as their new dependent claims 40-67, should be allowed, and Applicants respectfully request that they be passed to allowance.